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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/731,499	10/16/96	GRAY	J 023070-0689

18M1/0708  
TOWNSEND AND TOWNSEND AND CREW  
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EXAMINER	
DAVIS, M	
ART UNIT	PAPER NUMBER
1806	

DATE MAILED: 07/08/97

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This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on \_\_\_\_\_  
 This action is FINAL.  
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1835 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1 - 44 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) \_\_\_\_\_ is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims 1 - 44 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_.  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-23, drawn to an isolated nucleic acid molecule which specifically hybridizes under stringent conditions to a sequence of SEQ ID No: 2-12, classified in class 536, subclass 23.1.
  - II. Claims 24-38, and 42, drawn to a method of screening for neoplastic cells, using as a probe a sequence of SEQ ID No: 1-8, classified in class 435, subclass 6.
  - III. Claims 39-40, and 42, drawn to a method of screening for neoplastic cells, using as a probe an antibody against a polypeptide encoded by a sequence of SEQ ID No: 1-12, classified in class 435, subclass 7.1.
  - IV. Claims 41, 43, and 44, drawn to a method of treating cancer, classified in class 514, subclass 44.
2. The inventions are distinct, each from the other because of the following reasons:  
Inventions (I) and (II-IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a DNA sequence could be used for multiple purposes, e.g. for the

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detection of similar DNA or RNA sequences, for making an expression vector, for producing its encoded protein, and for treating cancer.

The methods of Groups II-III differ in the method objectives, method steps and parameters and in the reagents used. Groups II-III are drawn to a method of diagnosis of a disease, whereas group IV is drawn to a method of treating a disease. Diagnosis of a disease is not a therapeutic procedure and obviously differs in objectives from group VIII. Diagnosis of diseases requires biochemical assays and reagents and protocols that are different than those used for treatment of diseases. The method of group II is different from the method of group III because in group II a DNA sequence is used as a probe, whereas in group III an antibody is used as a probe. Clearly the objectives and reagents used in the three methods are distinct and would require different searches in the commercial data bases, as well as the patent shoes.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

A telephone call was made to Kevin L. Bastian on June 25, 1997 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted.

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Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[lila.feisee@uspto.gov\]](mailto:[lila.feisee@uspto.gov]).

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless **the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122**. This is more clearly set

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forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

July 5, 1996



A handwritten signature in black ink, appearing to read "Lila Feisee" followed by "JULY 5".

LILA FEISEE  
PRIMARY EXAMINER  
GROUP 1800